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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,456	01/05/2001	Frederic Delbac	1566-00	5009

35811 7590 04/19/2004

IP DEPARTMENT OF PIPER RUDNICK LLP  
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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/755,456	<b>Applicant(s)</b> DELBAC ET AL.	
	<b>Examiner</b> Mark Navarro	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 33-36 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 33-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Applicants amendment filed February 4, 2004 has been received and entered. Claims 2 and 4 have been canceled, and new claim 36 has been added. Consequently, claims 5 and 33-36 are pending in the instant application.

#### ***Claim Rejections - 35 USC § 112***

1. The rejection of claims 33-35 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions comprising the purified microsporidian polar tube protein consisting of amino acids 23-395, does not reasonably provide enablement for pharmaceutical compositions comprising the purified microsporidian polar tube protein consisting of amino acids 23-395 is maintained.

Applicants are asserting that, as is well known in the art, an antibody is a protein that is produced in response to an antigen, it is able to combine with and facilitate the clearance of the antigen. Applicants assert that it is common knowledge to those of less than ordinary skill in the art that antibodies provide protection against attack by a pathogen. Applicants have further enclosed a definition of an antibody.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants are asserting that, as is well known in the art, an antibody is a protein that is produced in response to an antigen, it is able to combine with and facilitate the clearance of the antigen. Applicants assertions are generally true. However, the claims are directed to a "pharmaceutical composition" which "prevents infection." Applicants

simple statements notwithstanding, eliciting an antibody does not equate with “protection.” Applicants are respectfully reminded that every single person living with HIV infection has an antibody titer to the HIV virus. However as known by those of less than ordinary skill in the art, these antibodies simply are not capable of eliminating or preventing HIV infection. This point has been further addressed by the teachings of Plotkin et al which set forth regarding vaccine production is that “The key problem is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of **protective** antibodies... and thus protect the host against attack.” (Emphasis added).

This point has been further addressed the courts: A vaccine “must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough.” In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Given that Applicants are attempting to claim a pharmaceutical composition that “prevents infections” a standard higher than a mere antigenic response is necessary, in view of the demonstrated unpredictability as to whether a single protein can achieve immunoprotection.

For reasons of record, as well as the reason set forth above, this rejection is maintained.

### ***Claim Rejections - 35 USC § 102***

2. The rejection of claims 2, 4, and 33-34 under 35 U.S.C. 102(b) as being anticipated by Delbac et al is withdrawn in view of Applicants amendment.

The following new ground of rejection is applied:

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 5 and 33-36 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 5 and 33-36 are directed to proteins which have the same characteristics and utility as proteins found naturally and therefore does not constitute as patentable subject matter.

In the absence of the hand of man, naturally occurring products are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Mere purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck Co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintergrating Co., 90 US 566 (1974); American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Inoculant Co. 33 US 127 (1948). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment to the claims to recite the essential purity of the claimed products is suggested to obviate this rejection. For example, "An isolated microsporidian polar tube protein..."


Claims 5 and 35 are objected to for reciting the amino acids 23-395 of SEQ ID NO: 1. Applicants paper copy of the sequence listing recites both a polynucleotide as

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SEQ ID NO: 1 and the encoded protein is translated underneath. However, electronically only the DNA sequence is identified. Accordingly, Applicant is required to identify the protein by its own appropriate designation. For examination, the DNA of SEQ ID NO: 1 was translated into a protein and searched.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro  
Primary Examiner  
April 16, 2004